

REMARKS

Applicants respectfully request entry of the amendments and remarks submitted herein. Claims 1 and 27 have been amended, and claim 28 has been canceled without prejudice to continued prosecution. Claims 1-27 are currently pending. Reconsideration of the pending application is respectfully requested.

The 35 U.S.C. §112 Rejections

Claims 1 and 27 stand rejected under 35 U.S.C. §112, second paragraph, as the Examiner asserted that those claims are indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. The Examiner asserted that it is unclear as to whether the claim is intended to be limited to hybridization of nucleic acid molecules or for labeling and identifying a solid, liquid, and gaseous substance as referred to in the preamble.

Claims 1 and 27 have been amended to correlate the steps of the method with the preamble. In view of the amendments herein, Applicants respectfully request that the rejection of claims 1 and 27 under 35 U.S.C. §112, second paragraph, be withdrawn.

Claim 17 stands rejected under 35 U.S.C. §112, second paragraph, as the Examiner asserted that claim 17 is indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants respectfully traverse this rejection.

The Examiner asserted that it is unclear how the second group of nucleic acid molecules can be bound to a solid surface if the first set of nucleic acid molecules are also contacting a substance that is a solid support, if the substance is broadly interpreted to encompass a solid support.

Applicants submit that claim 17 is clear. The method can be performed if N1-n and N'1-n are both attached to a solid surface.

In view of the remarks herein, Applicants respectfully request that the rejection of claim 17 under 35 U.S.C. §112, second paragraph, be withdrawn.

The 35 U.S.C. §102 Rejections

Claims 1-4, 8, 9, 12, 13, 20, 24, 26, and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by the methods of Sano et al. (U.S. Patent No. 5,665,539). Claims 1-11, 13-15, 20, 24, 26, and 27 stand rejected under 35 U.S.C. §102(b) as being anticipated by the methods disclosed in Slater et al. (WO 94/04918). Claims 1, 7-10, 13, 15, 17, 18, 20-23, and 27 stand rejected under 35 U.S.C. 102(b) as being anticipated by the methods described in Cantor et al (U.S. Patent No. 5,795,714). Claims 1, 2, 6, 16, 18, 24, and 25 stand rejected under 35 U.S.C. §102(b) as being anticipated by the method disclosed in Bumstead et al. (*J. Virological Methods*, 1997, 65:75-81). These rejections are respectfully traversed.

Sano et al. teaches a method for antigen detection using immuno-PCR in which a nucleic acid is used as a marker. Detection of the marker nucleic acid requires amplification and gel electrophoresis.

Slater et al. describes a method of marking a liquid and detecting the marked liquid. The marking generally includes a mixture of different synthetic nucleic acids. The nucleic acids are amplified by PCR and are then detected. The Examiner asserted that the variable region in the nucleic acid sequences used by Slater et al. for tagging correspond to Applicants' nucleic acid molecules selected from the first group. The Examiner further asserted that the primers used by Slater et al. for amplification of the labeled nucleic acid sequence correspond to Applicants' nucleic acid molecules from the second group (N'1-n).

Cantor et al. teaches a method for replicating an array of nucleic acid probes by immobilizing nucleic acids on a solid support. Cantor et al. teaches that such nucleic acids have a constant sequence and a random sequence. The nucleic acids are contacted with a primer that hybridizes to the constant sequence, and the primer is then enzymatically extended using the random sequence as a template. The extension product is denatured from the nucleic acid and fixed on a second solid support for detection.

Bumstead et al. describes conventional PCR amplification of a portion of a viral genome using fluorescently-tagged primers. According to the Examiner, the viral DNA corresponds to Applicants' nucleic acid molecules selected from the first group. The Examiner further asserted that the solution containing the viral genome corresponds to Applicants' labeled substance (S1-n).

The cited references all require PCR amplification for detection. The claimed methods differ from the cited references for several reasons. First, the claimed methods do not recite or require amplification. The amplification discussed in the specification refers to the optional amplification of N1-n prior to providing and contacting the labeled substance with the second group of nucleic acid molecules (N'1-n). In embodiments in which the N1-n molecule is amplified, two primer binding sequence sections (PBS1 and PBS2) on each side of IDS1-n are used (see, for example, claim 2). Second, the N1-n and N'1-n nucleic acid molecules are not the equivalent of primers, nor are the IDS1-n and IDP1-n sequence sections contained within the N1-n and N'1-n molecules, respectively. Rather, the IDS1-n and IDP1-n sequence sections are complementary to each other. With respect to the present invention, detection of the labeled substance is dependent upon whether or not the various IDS1-n and IDP1-n sequence sections hybridize with one another, and is not dependent upon their hybridization to and amplification of template DNA as the cited references teach.

The cited references do not teach or suggest a method for labeling and identifying a substance using the methods steps recited in the pending claims. According to the present invention, nucleic acids having a random sequence would not be used in the claimed methods. Random sequence nucleic acids would not allow for the identification of a substance (S1-n) as the pending claims recite. Enzymatic extension does not take place from N1-n, N'1-n, IDS1-n, or IDP1-n. The claimed invention allows for complex labels (e.g., labels having more than one nucleic acid molecule selected from the first group) to be detected.

The present invention is neither anticipated by nor obvious over Sano et al., Slater et al., Cantor et al., Bumstead et al., or any combination thereof. In view of the remarks herein, Applicants respectfully request that the rejection of claims 1-18 and 20-27 under 35 U.S.C. §102(b) be withdrawn.

Applicant : Wolf Bertling et al.
Serial No. : 10/048,035
Filed : January 22, 2002
Page : 8 of 8

Attorney's Docket No.: 10848-017001 / 412018GA-rp

CONCLUSION

Applicants respectfully request that claims 1-27 be allowed. Enclosed is a check in the amount of \$60 for the Petition for Extension of Time fee. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date:

March 16, 2005

M. Angela Parsons

M. Angela Parsons, Ph.D.

Reg. No. 44,282

Fish & Richardson P.C., P.A.
60 South Sixth Street, Suite 3300
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696